SEP 2 1 2004

510K(k) SUMMARY K042354

SUBMITTER:

Cresco Ti® Systems AB
Dobelnsgatan 7
Kristianstad, 29125
Sweden

DATE PREPARED: **August 25, 2004**

DEVICE NAME: **Modification to the CRESCO TI® IMPLANT**

CLASSIFICATION NAMES: CONCEPT **Endosseous Dental Implant & Accessories'T**

PREDICATE DEVICE: **CRESCO TI® IMPLANT CONCEPT**

Device Description:
The proposed system which is the subject of this Special 510(k) Notification, is a modification to the existing Cresco Ti implant concept, which has been previously cleared by the FDA under 510(k) Number K981052 on December 18, 2001. This concept includes a single non-sterile package containing all components necessary for the laboratory work and the prosthetic work to produce bridge supports and related accessories which are compatible with non-Cresco Ti endosseous implants. Modifications have been made to apply the same concept as that used for the Cresco Ti implant system to other implant interfaces other than those included on page B4 of the original 510(k) Notification K980152. Additional bridge supports are included in this 510(k) Notification which are designed to fit a broader range of implant interfaces. In addition, the Cresco concept can also be used for other metals or metal alloys in addition to Titanium (e.g. precious metal, Co-Cr),

Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated for use as a endosseous dental implant and associated accessories:

Device	510(k) Document Number	Date Cleared	Indications
Cresco Ti® Implant Concept	K981052	December 18th, 2001	**Endosseous Dental Implant & Accessories**

We therefore consider the proposed devices substantially equivalent and identical to existing products/predicate devices either currently or in the past, in commercial distribution in the United States

Intended Use:

Cresco Ti® Implant Concept Indications:

The Cresco Ti® Implant Concept is intended a) for implantation into the fully edentulous ridge for the support of a dental prosthesis: b) for implantation into the partially edentulous ridge for support of a dental prosthesis: a c) for single tooth implantation use

Technological Characteristics:

Technologically, both the proposed and predicate devices are the same and are indicated for use as endosseous dental implants and accessories. The modification to the above listed endosseous dental implant and accessories, extends the compatibility of the Cresco Ti screws and bridge supports to additional designs of dental implants provided by manufacturer's other than Cresco Ti Systems AB. Additionally, both devices utilize accessories for abutments, screws and bridge supports which are connected to the endosseous dental implants.

Summary of Non-Clinical Tests:

In vitro testing (mechanical and fatigue tests) has been performed to assess the validity of the design and the validity of the interface with the implant types interface such as external hex, internal hex, internal or external tapered cone. Additionally, careful screw design analysis has been carried out and a detailed torque angle signature analysis confirmed the validity and design of Cresco solutions.

Clinical Test Results:

Clinical testing demonstrate the long-term validity of the concept not only on Cresco platform, but also on external hex and internal tapered surface type platforms, such as Branemark and ITI systems.

Conclusions:

Any differences between the two devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2004

Ms. Jeanette Bengtsson
Quality Assurance/
Cresco Ti Systems AB
Döbelnsgatan 7
291 25 Kristianstad, Sweden

Re: K042354
Trade/Device Name: Modification to: Cresco TI® Implant Concept
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: June 1, 2004
Received: August 31, 2004

Dear Ms. Bengtsson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042354
Device Name: Cresco Ti® Implant Concept
Indications for Use:

The Cresco Ti® Implant Concept is intended

a) for implantation into the fully edentulous ridge for the support of a dental prosthesis;

b) for implantation into the partially edentulous ridge for support of a dental prosthesis;

c) for single tooth implantation use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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